REMARKS

Claims 1, 2, 4, 5, and 8 – 13 are currently pending. Claims 1, 2, and 9 are the pending independent claims.

I. Status of the Current Office Action.

The Applicants first wish to address the nature or status of the current Office Action, prior to addressing the merits of the comments therein. The previous Office Action in this case, dated February 17, 2009, was a non-final Office Action. The Applicants responded to the non-final Office Action on June 16, 2009, by amendment and argument. After this, the Patent Office next issued the current Action, which is labeled as an Advisory Action, on August 17, 2009.

It was the Applicants' believe that the Advisory status of this Action was improper since a final Office Action had not been issued following the Applicants submission of the June 16 amendment. Therefore, the Applicants' attorney, David Gonce, telephoned the Examiner on October 21, 2009 to discuss the procedural history of the case. During this conversation, the Examiner agreed that an Advisory Action would be improper at this stage. In an attempt to rectify the situation, the Examiner asked that the Applicants treat the Advisory Action as a final Office Action and respond accordingly. The Examiner also indicated that he would issue an Interview Summary to that effect and have the status of the case updated in PAIR.

The Applicants have accordingly prepared this response, treating the issues raised in the August 17 Action as final rejections.

The Applicants also wish to clarify that since the August 17 Office Action is taken as being a final Office Action, the Applicants would have until November 17, 2009, to respond without payment of extension fess and the time for response could be extended until February 17, 2009, by payment of appropriate fees. The Applicants request that the Examiner contact the undersigned if he believes the aforementioned deadlines for response are incorrect.

II. Response to the Issues Raised in the Current Office Action.

In the Action, the Examiner first contends that the addition of the limitation "core" in the claims raises the issue of new matter. In response, the Applicants note that while the word "core" is not explicitly recited in the specification, an explicit recitation of the word "core" is not necessary.

Whenever the issue of new matter or a lack of written description arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). In this regard, it is clear that the subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. *See* M.P.E.P. § 2163.02. Rather the courts have determined that by disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. *See* M.P.E.P. § 2163.07(a).

In the present case, the specification describes the preparation of micropellets comprising clarithromycin in Examples 1 – 3. The preparation of coatings is then described in Examples 4 and 5. Finally, in Example 6, the specification describes the application of coatings from Examples 4 and 5 to micropellets as prepared in Example 1. When the coatings are applied to the previously formed micropellets in this manner, those of ordinary skill will readily appreciate that the micropellets prepared in Example 1 are inherently functioning as cores upon which coatings may be applied. Thus, it is respectfully submitted that the limitation of a "core" is adequately described in the specification notwithstanding the fact that the word "core" is not expressly used in the specification. Accordingly, any new matter or written description rejections relating to this limitation should be withdrawn.

With regard to the prior art, the Applicants understand that the Examiner continues to reject of Claims 1, 2, 4, 5, and 8 – 13 as allegedly obvious over U.S. Patent No. 6,740,341 to Holt et al.

("Holt") taken in combination with U.S. Patent No. 6,565,877 to Mukherji et al. ("Mukherji").

As the Applicants have previously explained, the independent claims are directed to a taste masking composition calling for, among other things, micropellets including a core of one or more antibiotic particles coated with an inner cellulosic polymeric coating which in turn is coated with an enteric coating comprising an enteric coating polymer. This enteric coating dissolves in the intestine, not the mouth or stomach. This combination of coating layers has been found to provide effective taste masking.

Holt, the primary reference, does not teach or suggest the use of an enteric coating for taste masking. Instead, Holt explicitly directs that the taste masking layer should be a polymer (such as EUDRAGIT E-100) which is capable of rapidly dissolving in the stomach of a patient. (Holt, Column 6, Lines 12-13).

Mukherji, the secondary references, does not cure these deficiencies in Holt. While Mukherji discloses the existence of enteric materials, Mukherji proposes to use these enteric polymers by mixing them with an active ingredient to make a "fine dispersion." Mukherji does not teach the application of an outer "enteric" coating over a micropellet core.

Despite the foregoing, the Examiner, in the current Office Action, states that "there is no argument as to why the inclusion of the polymer taught by the secondary reference into the composition of the first would not be within the skill of the ordinary practitioner." However, this comment misstates the question. The issue is not whether an ordinary practitioner would have had the skill to use Mukherji's enteric polymer in Holt's formulation, but rather would he have had a motivation to use Mukherji's enteric polymer in Holt's formulation. As the Supreme Court has explained,

> a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, *it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does*. This is so because inventions in most, if not all, instances rely upon building blocks long since

> uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

KSR Intern. Co. v. Teleflex Inc., 127 S.Ct. 1727, 1741 (2007) (emphasis added).

In the present situation, there would not have been a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does because the teachings of Mukherji are essentially incompatible with the teachings of Holt regarding the structure of the micropellets. Holt's explicit purpose is to provide a formulation which releases an active ingredient in the stomach, not the intestine. Thus, once again, if Holt were modified with Mukherji as suggested by the Examiner, the resultant formulation would then be rendered inoperable for Holt's intended purpose. See *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

The Examiner also contends that "the secondary reference [Mukherji] was not used for its use of suspension as argued by applicant." The Applicants submit that the basis for this contention is not understood, as their previous Amendment of June 16, 2009, made no reference to the presence or absence of a suspension in the Mukherji reference.

Finally, it is noted that Claim 2 has been amended herein to specify that the antibiotic in the micropellets comprises clarithromycin. Holt, the Examiner's primary reference, makes no mention of clarithromycin. This limitation therefore provides an additional grounds by which Claim 2 distinguishes over the prior art, over and above the reasons set forth above.

In light of the foregoing, the present amendment is believed to place the application in a condition for allowance and entry of the foregoing amendments and allowance of Claims 1, 2, 4, 5, and 8 – 13 is respectfully solicited.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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